[F1ANNEX I]

MEDICINAL PRODUCTS TO BE AUTHORISED BY THE [F1UNION]

Textual Amendments

F1 Substituted by Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance).

1. Medicinal products developed by means of one of the following biotechnological processes:

— recombinant DNA technology,

— controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells,

— hybridoma and monoclonal antibody methods.

[F2 1a. Advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products](1)

Textual Amendments

F2 Inserted by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance).

2. Medicinal products for veterinary use intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals.

3. Medicinal products for human use containing a new active substance which, on the date of entry into force of this Regulation, was not authorised in the [F1Union], for which the therapeutic indication is the treatment of any of the following diseases:

— acquired immune deficiency syndrome,

— cancer,

— neurodegenerative disorder,

— diabetes,

— auto-immune diseases and other immune dysfunctions,

— viral diseases.

[F3After 20 May 2008, the Commission, having consulted the Agency, may present any appropriate proposal to amend this point and the European Parliament and the Council shall take a decision thereon in accordance with the Treaty.]

Textual Amendments

F3 Substituted by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance).

4. Medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

[F4ANNEX II

LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 84A

Textual Amendments

F4 Inserted by Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance).

(1) the obligation to submit complete and accurate particulars and documents in an application for marketing authorisation submitted to the Agency or in response to obligations laid down in this Regulation and in Regulation (EC) No 1901/2006 to the extent that the failure to comply with the obligation concerns a material particular;

(2) the obligation to comply with conditions or restrictions included in the marketing authorisation and concerning the supply or use of the medicinal product for human use, as referred to in point (b) of Article 9(4) and in the second subparagraph of Article 10(1);

(3) the obligation to comply with conditions or restrictions included in the marketing authorisation with regard to the safe and effective use of the medicinal product for human use as referred to in points (aa), (c), (ca), (cb) and (cc) of Article 9(4) and in Article 10(1);

(4) the obligation to introduce any necessary variation to the terms of the marketing authorisation to take account of technical and scientific progress and enable the medicinal products for human use to be manufactured and checked by means of generally accepted scientific methods, as provided for in Article 16(1);

(5) the obligation to supply any new information which may entail a variation to the terms of the marketing authorisation, to notify any prohibition or restriction imposed by the competent authorities of any country in which the medicinal product for human use is marketed, or to supply any information that may influence the evaluation of the risks and benefits of the product, as provided for in Article 16(2);

(6) the obligation to keep product information up to date with current scientific knowledge, including the conclusions of the assessment and recommendations made public on the European medicines web-portal, as provided for in Article 16(3);

(7) the obligation to provide, at the request of the Agency, any data demonstrating that the risk-benefit balance remains favourable, as provided for in Article 16(3a);

(8) the obligation to place the medicinal product for human use on the market in accordance with the content of the summary of the product characteristics and the labelling and package leaflet as contained in the marketing authorisation;

(9) the obligation to comply with the conditions referred to in Article 14(8)and Article 14-a;

(10) the obligation to notify the Agency of the dates of actual marketing and of the date when the medicinal product for human use ceases to be on the market, and to provide to the Agency data relating to the volume of sales and the volume of prescriptions of the medicinal product for human use, as provided in Article 13(4);

(11) the obligation to operate a comprehensive pharmacovigilance system for the fulfilment of pharmacovigilance tasks, including the operation of a quality system, maintenance of a pharmacovigilance system master file and performance of regular audits, in accordance with Article 21 of this Regulation in conjunction with Article 104 of Directive 2001/83/EC;

(12) the obligation to submit, at the request of the Agency, a copy of the pharmacovigilance system master file, as provided for in Article 16(3a);

(13) the obligation to operate a risk management system as provided for in Article 14a and Article 21(2) of this Regulation in conjunction with Article 104(3) of Directive 2001/83/EC and Article 34(2) of Regulation (EC) No 1901/2006;

(14) the obligation to record and report suspected adverse reactions for medicinal products for human use, in accordance with Article 28(1) of this Regulation in conjunction with Article 107 of Directive 2001/83/EC;

(15) the obligation to submit periodic safety update reports, in accordance with Article 28(2) of this Regulation in conjunction with Article 107b of Directive 2001/83/EC;

(16) the obligation to conduct post-marketing studies, including post-authorisation safety studies and post-authorisation efficacy studies, and to submit them for review, as provided for in Article 10a of this Regulation and Article 34(2) of Regulation (EC) No 1901/2006;

(17) the obligation to ensure that public announcements relating to information on pharmacovigilance concerns are presented objectively and are not misleading and to notify them to the Agency, as provided for in Article 22 of this Regulation and Article 106a(1) of Directive 2001/83/EC;

(18) the obligation to comply with the time limits for initiating or completing measures specified in the Agency's decision on deferral following the initial marketing authorisation of the medicinal product for human use concerned and in accordance with the definitive opinion referred to in Article 25(5) of Regulation (EC) No 1901/2006;

(19) the obligation to place the medicinal product for human use on the market within two years of the date on which the paediatric indication is authorised, as provided for in Article 33 of Regulation (EC) No 1901/2006;

(20) the obligation to transfer the marketing authorisation or to allow a third party to use documentation contained in the file of the medicinal product, as provided for in the first paragraph of Article 35 of Regulation (EC) No 1901/2006;

(21) the obligation to submit paediatric studies to the Agency, including the obligation to enter information on third country clinical trials into the European database, as provided for in Articles 41(1) and (2), 45(1) and 46(1) of Regulation (EC) No 1901/2006;

(22) the obligation to submit an annual report to the Agency as provided for in Article 34(4) of Regulation (EC) No 1901/2006 and to inform the Agency in accordance with the second paragraph of Article 35 of that Regulation.**]**

(1) **[**[F2]OJ L 324, 10.12.2007, p. 121.**]**

Textual Amendments

F2 Inserted by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance).

Status:
Point in time view as at 28/01/2019.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 726/2004 of the European Parliament and of the Council.